

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: NIKOLAI. AFANASENKO ET AL. (PCT)

SERIAL NO.: 08/646,213

GROUP: 3302

FILED: May 7, 1996

EXAMINER: J. CLARK

TITLE: DEVICE FOR TREATMENT OF PATIENTS WITH DISTURBED
POSTURE AND MOTOR ACTIVITY

DECLARATION UNDER RULE 132

ATTN: BOX FEE AMENDMENT
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, NODAR PETROVICH KAVTARADZE declare that since 1994, I have been Scientific Supervisor of the Rehabilitation Center, Professor, Member of the Medicobiological Academy of the Republic of Georgia; and

that the following clinical tests (EXHIBIT F) were conducted under my supervision:

EXHIBIT F

ANALYSIS

of the results of rehabilitation treatment
of patients with infantile cerebral paralysis,
using MK "Adeli" therapeutic Suit Children's
Fund Rehabilitation Center of the
Republic of Georgia

A treatment course was given to 40 patients with infantile cerebral paralysis who had been selected after a preliminary consultation with the participation of a neuropathologist, an orthopedist, a specialist in logopedics, and a pediatric psychologist, which was held from April 15 to May 15, 1995. Examination was performed twice, at the beginning and end of the treatment course.

The exercise treatment session of patients wearing the "Adeli" suit had a duration of from 120 to 150 minutes. The treatment course included complex rehabilitation with the use of laser acupuncture, microwave resonance therapy, paraffin bath, and fangotherapy with various kinds of muds. The specialist in logopedics and the psychologist were those who took an active part

in the treatment process (individual and group sessions).

The patients' age bracket was from 4 to 27 years old, including 20 children aged from 4 to 7 years old, 14 children aged from 8 to 14 years old, and 6 patients aged from 15 to 27 years old. There were 23 female and 17 male patients.

In a total of 40 patients with infantile cerebral paralysis, 21 patients suffered from spastic diplegia, 8 patients, from hemiplegia, and 11 patients, from hyperkinetic form. A general assessment of amelioration of the locomotorium is present in Table 1 below.

Table 1

Form of ICP	Number of patients	Degree of improvement			
		0	1	2	3
Spastic diplegia	21	2	6	7	6
Spastic hemiplegia	8	-	2	4	2
Hyperkinetic form	11	2	3	2	4
Total	40	4	11	13	12

Note: 0 indicates no effect, 1, for slight improvement, 2, for improvement, and 3, for considerable improvement.

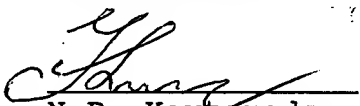
Ten patients out of 40 were devoid of the walking function; and a final examination revealed that three patients of the group could walk spontaneously. 18 patients were devoid of ability to walk spontaneously. A final examination revealed that 12 patients could walk much better after treatment. Another five patients walking with crutches before treatment could walk unassistedly after treatment.

Thus, it can be concluded that the treatment technique with Adeli yielding such improved results in treating the late

residual stage of infantile cerebral paralysis, is the most effective and efficient among all those treatments utilized at present.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 28.02.982


Name: N.P. Kavtaradze
Title: Scientific Supervisor of the
Rehabilitation Center, Professor,
Member of the Medicobiological Academy
of the Republic of Georgia